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Section B

510(k) Summary
Required by 21 CFR §807.92

I. Submitter:

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on behalf of Medisystems Corporation

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II. Date of preparation of this Summary: July 25, 1995

III. Trade Name: Arterial - Venous Blood Tubing Set

IV. Common Name: Tubing set

V. Classification Name: Set, Tubing, Blood, with and without Antiregurgation Valve

VI. The Marketed Device(s) to which Equivalence is Claimed: The blood tubing sets which are the subject of this submission are substantially equivalent to Medisystems blood tubing sets in commercial distribution pursuant to a prior premarket notification that was cleared on September 8, 1981.

VII. Product Description: Medisystems blood tubing sets are used during extracorporeal procedures by providing a means to connect blood access devices to flow-through treatment device(s) (e.g. a hemodialyzer).

VIII. Statement of Intended Use Compared to Legally Marketed Device: The intended use of the Medisystems blood tubing set is identical to that of the legally marketed predicate device: The blood tubing sets are intended for use with a blood access device and a medically approved flow-through treatment device.

IX. Discussion of Technological Characteristics: Because the intent of this 510(k) is to seek FDA acknowledgment for a change in the labeling of currently marketed devices, the technological

characteristics of the device are unchanged. The specific proposed labeling changes consist of the following:

A. The directions for use have been expanded to provide the user with an increased amount of information concerning the use of the device.

B. Additional warnings and precautions are proposed to better inform the user of current information regarding hemodialysis procedures and to comply with the labeling requirements of ANSI/AAMI RD-17, Hemodialyzer Blood Tubing.

X. Safety and Effectiveness: The proposed changes to the blood tubing sets consist of modifications to the case insert label. The proposed labeling changes do not affect the product's design, composition, manufacturing, or performance characteristics. The labeling revisions are proposed to provide the user with an increased amount of information concerning the use of the device. Although none of the label changes raise new issues regarding safety and effectiveness, additional warnings and precautions are proposed to better inform the user of recent trends in dialysis procedures involving high efficiency or high flux dialysis and to be consistent with recognized standards.